



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2270]

The Drug Supply Chain Security Act Implementation: Product Tracing Requirements for Dispensers--Compliance Policy; Updated Guidance for Industry, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; revised guidance document.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a revised guidance document that extends the compliance policy described in the guidance for industry entitled “DSCSA Implementation: Product Tracing Requirements for Dispensers--Compliance Policy.”

This revised guidance announces FDA’s intention with regard to enforcement of certain product tracing requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) added by the Drug Supply Chain Security Act (DSCSA). FDA does not intend to take action against dispensers who, prior to March 1, 2016, accept ownership of product without receiving transaction information, transaction history, and transaction statements (product tracing information), prior to or at the time of a transaction, or do not capture and maintain the product tracing information, as required by the FD&C Act.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For information about enforcement dates, please see the SUPPLEMENTARY INFORMATION section.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-2270 for “The Drug Supply Chain Security Act Implementation: Product Tracing Requirements for Dispensers--Compliance Policy; Revised Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 6, 2015, FDA published a Notice of Availability in the Federal Register (80 FR 38449) announcing a guidance document entitled “DSCSA Implementation: Product Tracing Requirements for Dispensers--Compliance Policy.” The guidance described FDA’s intention with regard to enforcement of the product tracing information requirements under section 582(d)(1) of the FD&C Act (21 U.S.C 360eee-1(d)(1)). FDA is issuing a revised guidance that extends the compliance policy described in the guidance. We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). We made this determination because this guidance document provides information pertaining to certain statutory requirements that took effect on July 1, 2015, regarding the provisions to provide, capture, and maintain product tracing information under section 582(d)(1) of the FD&C Act, and it extends a compliance policy that would have expired for transactions after November 1, 2015. It is

important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices (21 CFR 10.115(g)(3)).

On November 27, 2013, the DSCSA (Title II of Pub. L. 113-54) was signed into law. Section 202 of DSCSA adds sections 581 and 582 to the FD&C Act, which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) were required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to exchange product tracing information when engaging in transactions involving certain prescription drugs. For dispensers, requirements for the tracing of products through the pharmaceutical distribution supply chain under section 582(d)(1) of the FD&C Act took effect on July 1, 2015. FDA published a guidance document on July 6, 2015, stating that it does not intend to take action against dispensers who, prior to November 1, 2015, (1) accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act, or (2) do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act.

Some dispensers--primarily smaller, independent pharmacies and health systems--have expressed concern that they will be unable to comply with these requirements by November 1, 2015. Thus, FDA recognizes that these dispensers continue to need additional time to work with trading partners to ensure that the product tracing information required by section 582 of the FD&C Act is captured and maintained by dispensers. In light of these concerns, FDA does not intend to take action against dispensers who, prior to March 1, 2016: (1) accept ownership of product without receiving product tracing information, prior to or at the time of a transaction, as

required by section 582(d)(1)(A)(i) of the FD&C Act or (2) do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act. This compliance policy does not extend to other requirements of the FD&C Act applicable to dispensers and other trading partners, including those in section 582 of the FD&C Act, such as verification related to suspect and illegitimate product (including quarantine, investigation, notification, and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners. The guidance document explains the scope of the compliance policy in further detail.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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